Carolinas Medical Center
Carolinas HealthCare System

Department of Obstetrics and Gynecology

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December 20, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane Room 1061
Rockville, MD 28252

RE: Docket #97N-484S, Suitability Determination for Donors of Human Cellular and Tissue Based Products

To whom it may concern:

I am strongly opposed to a section in the proposed rules regarding donor oocytes for IVF, described in "Suitability Determination for Donors of Human Cellular and Tissue-Based Products," regarding the requirement to cryopreserve and quarantine donor oocytes.

Why would the FDA impose such a requirement? Has there been even a single case reported in the world's medical or lay literature describing the transmission of HIV, Hepatitis, or any other sexually transmitted disease by oocyte donation? This type of report, if it existed, would demand immediate attention from our medical societies as occurred with the transmission of HIV with fresh semen. To my knowledge, there is no report in any source that has indicated that oocyte donation is a risk.

What would be the harm of such an imposition of donor oocyte cryopreservation and quarantine? Pregnancy and delivery rates would be markedly lowered with cryopreservation, compared to fresh cycles. In our program, the delivery rates would be lowered by more than one-half. Our outcomes are comparable to national outcomes.

As success for these procedures is lowered, the cost for success skyrockets. Oocyte donation is already a very expensive procedure. If a requirement to cryopreserve embryos were imposed by the FDA, oocyte donation would become limited to the extremely wealthy.

I totally support use of the guidelines of oocyte donor selection and screening recommended by the America Society of Reproductive Medicine. If the FDA mandates screening, these are the guidelines that should be considered.

Sincerely,

Bradley Hurst

Bradley S. Hurst, M.D.
Director, Assisted Reproductive Technology
Associate Director, Reproductive Endocrinology

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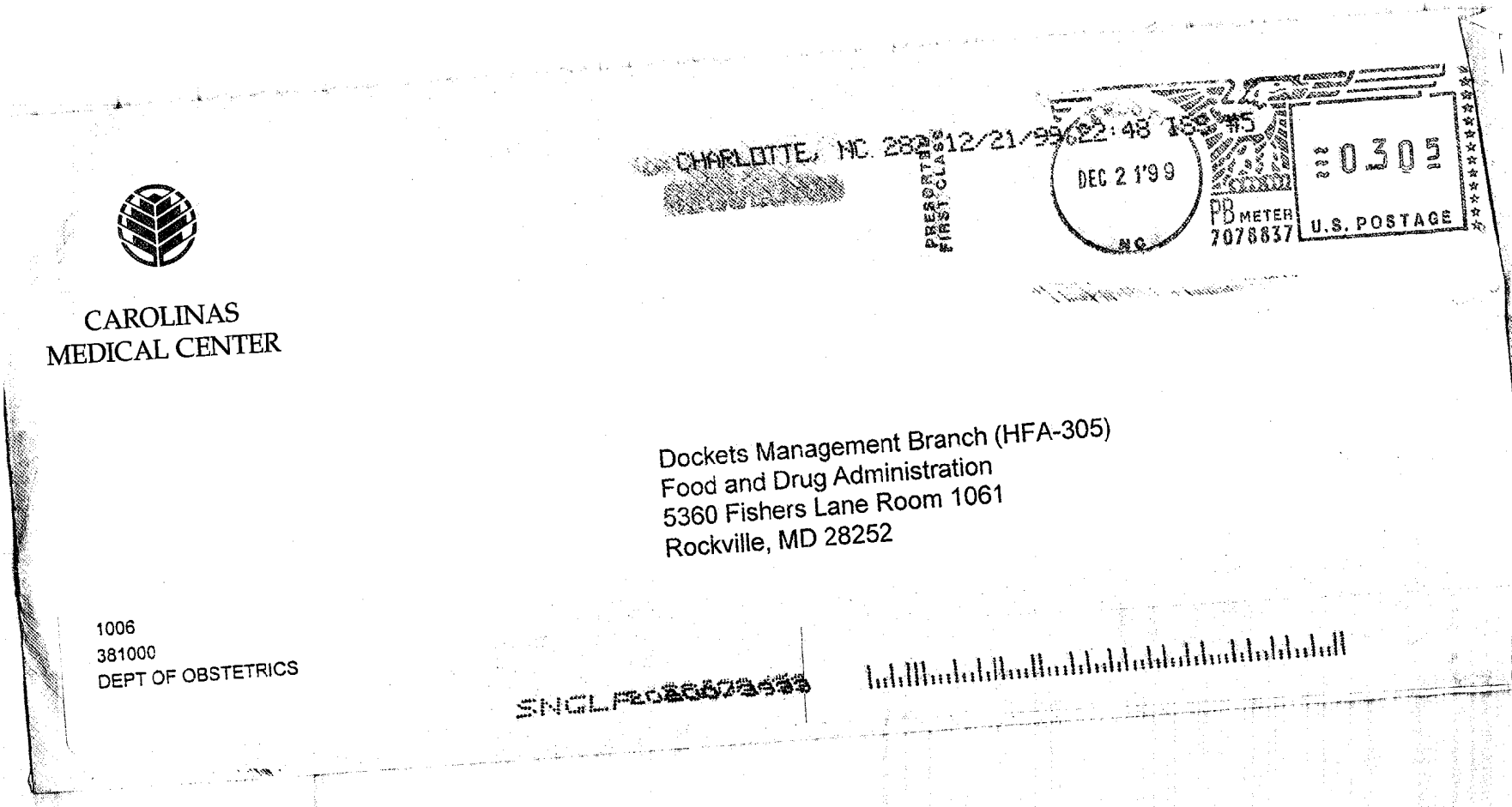
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